



August 31, 2018

Michael Goodis, Director
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Anita Pease, Acting Director
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PV Shah, Branch Chief
CITAB/RD/OPP/EPA
1200 Pennsylvania Ave
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RE: Formulation with preservatives; follow up

Dear Mr. Goodis, Ms. Pease, and Dr. Shah:

We thank EPA for the August 23 response to our letter of July 27, 2018, asking for accommodations based on the market disruption for BIT. Representatives of CropLife America (CLA), the Center for Biocide Chemistries (CBC), the Council of Producers & Distributors of Agrotechnology (CPDA), the Household & Commercial Products Association (HCPA), RISE (Responsible Industry for a Sound Environment), and the Biological Products Industry Alliance (BPIA) have reviewed the letter and have questions as detailed below. Since our initial letter, the situation has become more serious, as many formulators will not be able to procure BIT for their products. As a result, the Agency's response allowing self-certification of changes in BIT supply for pesticide formulations, while a necessary and welcome first step, provides only limited, short-term, temporary relief. We request that the clarifications and additions discussed herein be incorporated into a revised letter or supplement to EPA's August 23 letter.

1. While there is great focus on ways to utilize the available BIT supply, we must be able to quickly and efficiently switch to other preservative chemistries in pesticide formulations, as long as BIT is in short supply. Ideally, EPA will accommodate changes by self-certification, but if not, we must find other creative solutions. Skipping or skimping on preservative use can lead to serious consequences for product integrity, worker exposure, and efficacy in the field. Many biopesticides contain naturally-derived ingredients that require preservatives to inhibit decomposition. Lack of alternative preservatives brings pesticide production to a halt. Pesticide users would lose access to hundreds of essential products, as registrants halt

production, pending the Agency's review and approval of the hundreds of amended CSFs. This situation will require brainstorming among registrants, suppliers, and regulators, to find solutions that may not be readily apparent. The recommendations we make here are not all "shovel-ready." We ask that there be a continuous dialogue to achieve resolution, rather than relying on exchange of letters and emails, which leads to several days delay between responses.

- a. Strategies for BIT-free preservatives used as inerts: Allow substitution of BIT-free products that are registered for use in pesticide formulations and have the appropriate tolerance exemptions, by expedited procedures. These could include MIT, CIT, bronopol, combinations thereof, and perhaps others.
2. BIT production needs to be restored as quickly as possible. To that end, we ask that new BIT precursor production facilities be allowed for BIT technical registrations by self-certification. We assume this issue is in the purview of the Antimicrobials Division and perhaps deserves separate guidance from the Agency.
3. For BIT as an **active ingredient**, the list provided by EPA fails to include BIT technical or manufacturing-use products (MUPs). Instead of a listing, we ask that EPA clearly state that all registered BIT technical products and MUPs are acceptable as alternative sources of BIT for formulated BIT products.
4. For BIT as an **inert ingredient**, we understand from your conversation with Gary Halvorson of CPDA on Friday, Aug 24, that EPA intends to allow other registered BIT products in the 19 to 20.5% concentration range, in addition to those specifically listed. We request that the Agency explicitly allow self-certification for changing the source to any registered BIT product in the 19 to 20.5% concentration range, including sub-registrations.
5. Switching to alternative BIT products does not get us past the extremely short supply of BIT, with competition from several industries that use it as a preservative in a range of industrial and consumer products. Many of those products have a wider choice of ingredients to satisfy preservative needs, because they are not dependent on the tolerance exemption for use on food crops. Therefore, we ask that EPA consider the following strategies for "stretching" the supply of BIT:
 - a. Other BIT products outside the 19 to 20.5% active ingredient concentration range are also registered for use in pesticide formulations. These should be allowed as substitutes by self-certification as well, so long as any difference in formulation content percentage will be made up by adjusting a filler ingredient.
 - b. Allow substitution of BIT/CIT/MIT combination products by self-certification.
6. As with industrial uses, similar strategies could apply to FIFRA-registered products which currently use BIT as a preservative and are registered only for non-food-crop uses. Because a tolerance exemption is not needed, a wider choice of alternatives, including other preservative ingredients, should be allowable as substitutes by self-certification, so long as any difference in formulation content percentage will be made up by adjusting a filler ingredient. The self-certified changes could be verified by subsequent submission of an alternative CSF for appropriate review and approval.

7. Formulation of a registered pesticide product can include both direct and indirect sources of preservative ingredients. Formulators use microbicides directly, like those above, which appear on CSFs for the registered pesticide products. Formulators also purchase other inert ingredients as mixtures or proprietary blends, such as pigment dispersions, surfactant solutions, antifoam emulsions, etc., that also rely on these same or similar preservatives. CITAB maintains the compositions of such mixtures in confidential "master files". EPA should likewise issue separate guidance allowing the suppliers of such mixtures that may contain BIT-based preservatives to submit alternative compositions to CITAB by self-certification, based on the same considerations as above. Without such a provision, many registered pesticide products could not be formulated, should these inert mixtures become unavailable.
8. EPA should admit additional registered preservative products to its confidential "master files" of approved proprietary blends of inert ingredients, so that they can be used in pesticide formulations without concern by the formulator about the precise content of those products.

Sincerely,



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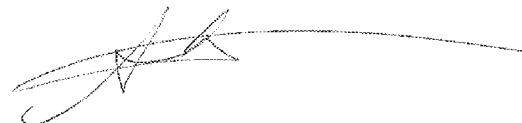
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